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May 21, 1999

BY FACSIMILE/CONFIRMATION COPY BY FIRST CLASS MAIL

George Q. Mills, M.D.
Center for Biologics Evaluation and Research
Food and Drug Administration
1401 Rockville Pike, Room 200N
Rockville, Maryland 20852

Re: Draft "Guidance For Industry: Developing Medical Imaging Drugs and
Biologics" (Docket No. 98D-0785)

Dear Dr. Mills:

In its initial comments on the above referenced guidance, the Council on Radionuclides and Radiopharmaceuticals (CORAR) undertook to submit to FDA a proposed decision tree relating to the degree of clinical and other information that should be provided to an independent, blinded reader. The proposed decision tree is enclosed. We are also sending you a copy by electronic mail. Please call if you have any questions about the decision tree.

Sincerely,



Alan Kirschenbaum

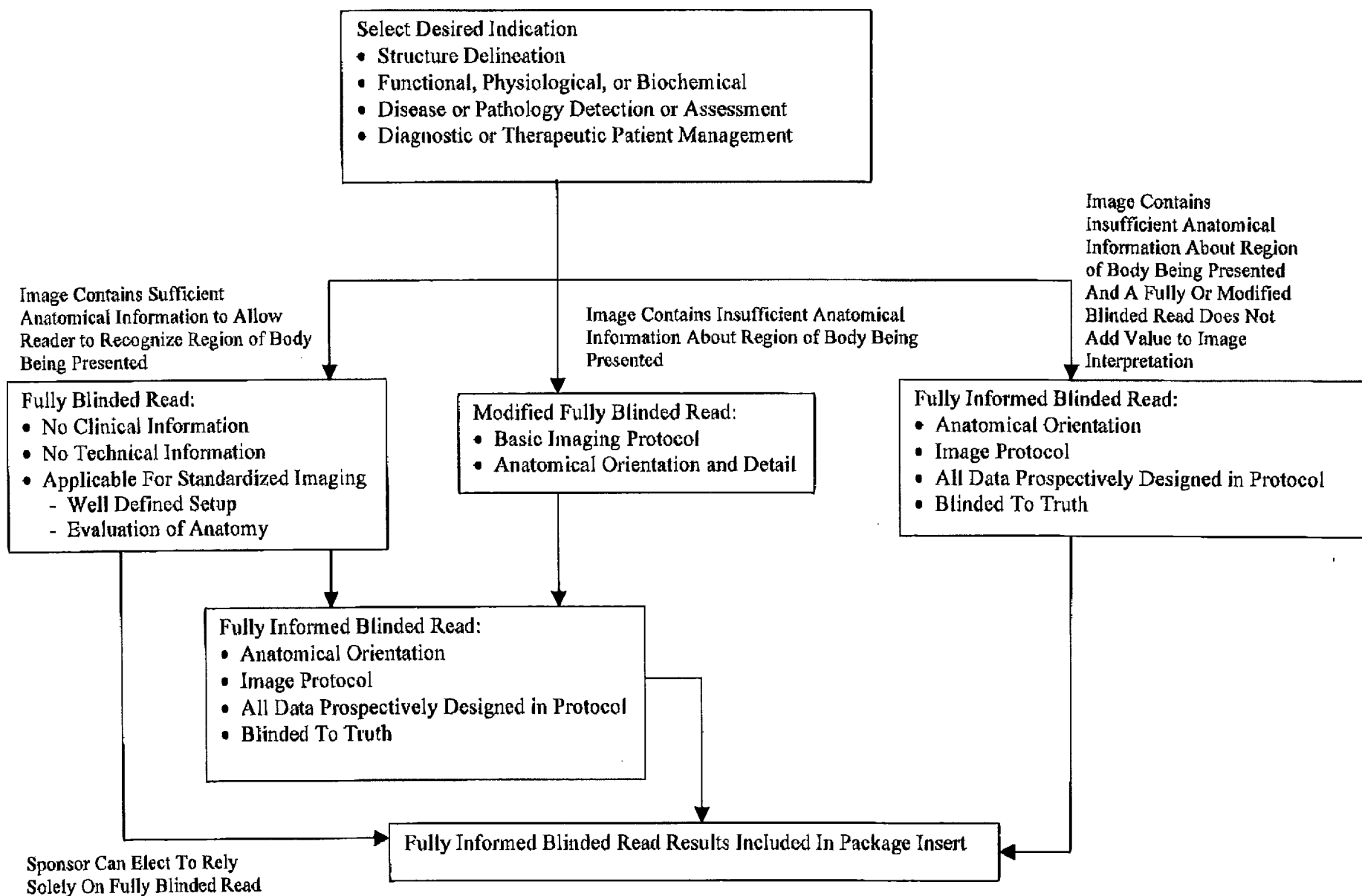
AMK/dmb

cc: Jane A. Axelrad (by facsimile)
Rebecca A. Devine, Ph.D. (by facsimile)
Patricia Y. Love, M.D. (by facsimile)
Dockets Management Branch

98D-0785

LET3

Blinded Read Decision Tree





Playtex Products, Inc.

Technical Center, 75 Commerce Dr.
Allendale, New Jersey 07401-1600

May 19, 1999

5074 '99 MAY 21 09:14

Mridulika Virmani, Ph.D.
Food and Drug Administration
Division of Reproductive, Abdominal, Ear, Nose
And Throat and Radiological Devices
9200 Corporate Blvd. – HFZ 470
Rockville, MD 20850

Mark E. Rosengarten
Director
Regulatory & Biomedical Affairs
Research & Development
201 785-8040
Fax: 201 785-8212
rosengm@playtexproductsinc.com

Dear Dr. Virmani:

As per our conversation of May 12, 1999, you have requested the following information from Playtex Products, Inc.:

- The brand names of all tampons we currently sell.
- The 510(k) numbers for all currently sold tampons.
- The identity of fiber and fiber blends we use in currently sold tampons.
- Do we sell only to retail customers, or do we contract manufacture?
- What is the location of our current manufacturing site(s) for tampons?

The following information is being provided in response to your request for information. Playtex Products, Inc. sells tampons retail under the following brand names:

- | | |
|---|----------|
| • Playtex Gentle Glide Deodorant Tampons | K964269. |
| • Playtex Gentle Glide Non-Deodorant Tampons | K912002. |
| • Playtex Gentle Glide Odor Absorbing Tampons | K980478. |
| • Playtex Gentle Glide SlimFits Deodorant Tampons | K961870. |
| • Playtex Gentle Glide SlimFits Non-Deodorant Tampons | K961870. |
| • Playtex Gentle Glide Multi-Pack Deodorant Tampons | K941196. |
| • Playtex Gentle Glide Multi-Pack Non-Deodorant Tampons | K941196. |
| • Playtex Portables Regular and Super Deodorant Tampons | K881057 |
| • Playtex Portables Regular and Super Non-Deodorant Tampons | K881057 |
| • Playtex Portables Super Plus Deodorant Tampons | K891297. |
| • Playtex Portables Super Plus Non-Deodorant Tampons | K891297. |
| • Playtex Silk Glide Deodorant Tampons | K950928. |
| • Playtex Silk Glide Non-Deodorant Tampons | K950928. |
| • Playtex Silk Glide Odor Absorbing Tampons | K981760. |

Playtex Products, Inc. does serve as the contract manufacturer for a number of private label brands. These products are covered under the Silk Glide 510(k)s listed above respectively.

Playtex tampons are manufactured at: Playtex Products, Inc.
50 North Dupont Highway
P O Box 7016
Dover, Delaware 19903-1516.

We hope this information is helpful. Please let me know if I can be of any further assistance.

Sincerely,

A handwritten signature in black ink, appearing to read 'M. Rosengarten', with a long horizontal flourish extending to the right.

Mark Rosengarten

cc: Dr. Irwin Butensky – Playtex Products, Inc.

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FROM: Alan M. Kirschenbaum

DATE: May 21, 1999

TO: George Q. Mills

FAX NO.: 301-827-2801

CC: Patricia Y. Love, M.D.
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